

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PURDUE PHARMA PRODUCTS L.P.,  
NAPP PHARMACEUTICAL GROUP LTD.,  
BIOVAIL LABORATORIES INTERNATIONAL,  
SRL, and ORTHO-MCNEIL, INC.,

Plaintiffs/Counterclaim-defendants,

v.

PAR PHARMACEUTICAL, INC. and  
PAR PHARMACEUTICAL COMPANIES, INC.,

Defendants/Counterclaim-plaintiffs.

C.A. No. 07-255-JJF  
(CONSOLIDATED)

**DECLARATION OF DR. MARTYN C. DAVIES IN SUPPORT OF  
PLAINTIFFS' ANSWERING BRIEF ON CLAIM CONSTRUCTION**

I, Martyn C. Davies declare pursuant to 28 U.S.C. § 1746 that:

1. I am the same Martyn C. Davies who submitted a declaration in support of Plaintiffs' Opening Brief On Claim Construction on June 13, 2008. I am qualified in all respects to make this declaration and have personal knowledge of the facts set forth herein, except as specifically stated otherwise.

2. I make this declaration in support of Plaintiffs' Answering Brief On Claim Construction. I hereby incorporate by reference all the paragraphs set forth in my June 13, 2008 declaration.

3. I have read Defendants' Opening Claim Construction Brief and the Declaration Of Michael L. Weinberger, M.D. In Support Of Defendants' Opening Claim

Construction Brief. In this declaration, I do not attempt to discuss each and every disagreement that I have with Par's proposals or with Dr. Weinberger's declaration.

4. Par's proposed definition of "matrix" is based on a textbook definition of one type of a controlled release matrix, citing to Yihong Qiu and Guohua Zhang, *Research and Development Aspects of Oral Controlled-Release Dosage Forms*, in the Handbook of Pharmaceutical Controlled Release Technology. The term "controlled release matrix" is a term with a commonly understood meaning in the pharmaceutical arts. By contrast, "normal release matrix" is not a term of art to persons of ordinary skill. As explained in paragraphs 31 and 33 of my June 13, 2008 declaration, a "normal release matrix," as described in the specification of the patents in suit, refers to what one of ordinary skill in the art would understand to be an immediate release formulation.

5. As explained in my previous declaration, the patent specification describes both a controlled release matrix and a normal release matrix. Therefore, the meaning of "matrix" is linked to the function performed by it – either a controlled release or a normal release function. Par's proposed definition excludes one of the specified functions of a matrix, i.e., that of a normal release matrix.

6. The parties' agreed-upon construction of "substrate" is "a solid pharmaceutical preparation that contains the active ingredient." I agree with this definition. I disagree with Par's contention that Plaintiffs' proposed construction of "matrix" is redundant with the parties' agreed-upon construction of "substrate."


7. As explained in paragraphs 30-33 of my June 13, 2008 declaration, I agree with Plaintiffs' proposal that "matrix" means "a pharmaceutical preparation that incorporates the active ingredient dispersed within a solid dosage form." As explained above, the meaning of

“matrix” is linked to the function performed by it. Plaintiffs’ proposal incorporates this function by connoting that the active ingredient is incorporated into the pharmaceutical preparation by being dispersed (i.e., distributed) within the dosage form. A “dispersion” has a specific meaning to a person of ordinary skill in the art. In a “dispersion,” the particles are distributed within the matrix.

8. By contrast, the parties’ agreed upon definition of “substrate” does not require that the active ingredient be distributed *within* the dosage form. This is because the word “contains” does not specify *how* the active is contained in the preparation. Therefore, a substrate and matrix are not synonymous.

9. My understanding is consistent with the claim language and specification of the patents in suit. In the context of the claim language, e.g., ‘887 patent, claim 1, a substrate is something that is available to be coated by the claimed controlled release coating. One example of a substrate is found at col. 4, lines 56-59 of the ‘887 specification. The specification discusses an active ingredient coated or loaded onto inert nonpareil beads which are, in turn, coated with a controlled release layer. In this example, the drug coated nonpareil beads are the substrate because they “contain” the active ingredient and also, they are available to be subsequently coated with a controlled release layer. The nonpareil beads are not a matrix however as the drug is not dispersed within the nonpareil beads. Therefore, a substrate and a matrix are not synonymous.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct. Executed on July 2, 2008 in Nottingham, England.

A handwritten signature in black ink, appearing to read 'MCDavies', is written over a horizontal line.

MARTYN C. DAVIES

**CERTIFICATE OF SERVICE**

I hereby certify that on July 2, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Frederick L. Cottrell, III, Esquire  
Steven J. Fineman, Esquire  
RICHARDS, LAYTON & FINGER, P.A.

Richard D. Kirk, Esquire  
BAYARD, P.A.

Mary W. Bourke, Esquire  
CONNOLLY BOVE LODGE & HUTZ LLP

I further certify that I caused to be served copies of the foregoing document on July 2, 2008, upon the following in the manner indicated:

Frederick L. Cottrell, III, Esquire  
Steven J. Fineman, Esquire  
RICHARDS, LAYTON & FINGER, P.A.  
One Rodney Square  
Wilmington, DE 19801

*VIA ELECTRONIC MAIL*

Edgar H. Haug, Esquire  
Robert E. Colletti, Esquire  
FROMMER LAWRENCE & HAUG LLP  
745 Fifth Avenue  
New York, NY 10151

*VIA ELECTRONIC MAIL*

Richard D. Kirk, Esquire  
BAYARD, P.A.  
222 Delaware Avenue  
Suite 900  
Wilmington, DE 19801

*VIA ELECTRONIC MAIL*

Mary W. Bourke, Esquire  
CONNOLLY BOVE LODGE & HUTZ LLP  
The Nemours Building  
1007 North Orange Street  
Wilmington, DE 19801

*VIA ELECTRONIC MAIL*

*/s/ Rodger D. Smith II*

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Rodger D. Smith II (#3778)